CLINICAL LABORATORY PRACTITIONERS

SUNRISE REVIEW

BACKGROUND

The state legislature grants credentialing of health professionals after considering recommendations from the State Department of Health and the State Board of Health. Authority for review by the Department of Health and Board of Health is contained under RCW 18.120.040.

It is the legislature's intent that all individuals be permitted to enter into a health profession unless there is an overwhelming need for the state to protect the interest of the public by restricting entry into the profession. Where such a need is identified, the regulation adopted by the state should be set at the least restrictive level consistent with the public interest to be protected. Enhancements of professional status or qualification for third party reimbursement alone are unacceptable motives for regulation.

The Sunrise Act, RCW 18.120.010, states that a health profession should be regulated only when:

1. Unregulated practice can clearly harm or endanger the health, safety or welfare of the public and the potential for harm is easily recognizable and not remote or dependent upon tenuous argument;

2. The public can reasonably be expected to benefit from an assurance of initial and continuing professional ability;

3. The public cannot be effectively protected by other means in a more cost beneficial manner.

There are three types of credentialing:

1. Registration: A process by which the state maintains an official roster of names and addresses of the practitioners in a given profession; the location, nature and operation of the health activity practiced; and, if required by the regulatory entity, a description of the service provided. A registrant is subject to the Uniform Disciplinary Act, Chapter 18.130 RCW.

2. Certification: A voluntary process by which the state grants recognition to an individual who has met certain qualifications. Certification protects a title. Non-certified persons may perform the same tasks, but may not use "certified" in the title. A certified person is subject to the Uniform Disciplinary Act, Chapter 18.130 RCW.

3. Licensure: A method of regulation by which the state grants permission to persons who meet predetermined qualifications to engage in a health profession which would otherwise be unlawful in the absence of the permission. Licensure protects the scope of practice and the title. A licensee is subject to the Uniform Disciplinary Act, Chapter 18.130 RCW.

PROCESS

The Department of Health reviews health profession credentialing proposals only when requested by the Governor or the Chairs of the legislative health committees. Applicant groups who want their data and viewpoints reflected in departmental analysis must comply with submission deadlines and submit material directly to department staff. A public hearing is held to enable interested groups to testify and exchange views.

The Department's recommendations are not limited to deciding whether the applicant groups should be credentialed and the level of credentialing. The Department may also make recommendations on other portions of the proposed bill, such as:

1) whether the applicant group should be combined with other credentialed or applicant groups;
2) whether the proposed scope of practice should be broadened or narrowed;

3) whether the proposed licensing board or other proposed regulatory entity is appropriate and represents consumer interests.

The burden of proof is the applicant's responsibility. It is therefore the applicant's responsibility to provide all information necessary for the Department to complete the review process and prepare its findings and recommendations.

The proposed final draft is reviewed by the Executive Team of the Department of Health, and adopted, (with amendments if necessary), by the Secretary.

The final report, which includes the analysis and recommendations, is reviewed by the Office of Financial Management and approved by the Office of the Governor. The report is then provided to the legislature with amendments required by the Governor. The legislature uses the department's recommendations in evaluating and acting on the legislation.

Copies of the report are also provided to the applicant groups and other interested parties.

OVERVIEW OF PROCEEDINGS

On March 15, 1991 The Department of Health received a letter from Senator James West, Chair, Health and Long-Term Care Committee. This letter requested that the Department of Health conduct a sunrise review of SB 5907. SB 5907 is legislation

requested by the Washington State Society for Medical Technology which proposes to create a health professional licensing program for clinical lab science practitioners. Clinical lab science practitioners include: clinical laboratory scientists, clinical laboratory technicians, medical technologists, and anyone else performing clinical laboratory tests.

A meeting by department staff with Joan H. Gaumer, representing the Washington State Society for Medical Technology was held on April 16, 1991. Discussion at this meeting included a review of the department's time schedules for completion of the various aspects involved in accomplishing the Sunrise Review and the type of information and criteria needing to be submitted and addressed by the proponents.

Information was requested from other states regarding the results of any sunrise reviews and other information which would be useful in evaluating the proposal. Additionally, a subsequent letter was mailed to states not responding.

After staff completed review of the proposal and relevant material submitted by the proponents, additional clarifying information was requested of the proponents. Additionally, clarifying information was requested from various agencies, associations and organizations.

A sunrise review committee composed of staff from the Department of Health's programs; Licensing and Certification, Health Information, the State Public Health Laboratory, and health Promotion and Disease Prevention; was established and a

public hearing was held on August 22, 1991. An individual representing the Board of Health also participated on the committee to prevent duplication of process and to facilitate review. Verbal and written testimony was presented by proponents, opponents and neutral parties. All in attendance were given the opportunity to express their views on the proposal and elicit answers to questions they had relating to the proponents proposed regulation.

Interested parties were given an additional ten days to submit final comments to the committee and final draft recommendations were prepared for presentation to the Department of Health Executive Team/Secretary. A copy of the final draft recommendations was also forwarded to the Board of Health for their consideration and use. A formal presentation regarding the sunrise process and recommendations was provided to the Board of Health on October 9, 1991.

SUMMARY OF PROPOSAL

The proponents submitted alternative draft legislation to replace the proposed SB 5907. The proposal, in summary is:

Establish a licensing requirement for:

- Clinical Laboratory Scientists,
- Medical Technologists,
- Categorical Clinical Laboratory Scientists/Medical Technologists,

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- Medical Laboratory Technicians,
- Categorical Clinical Laboratory Technicians/Medical Laboratory Technicians,
- Laboratory Assistants,
- Level I Personnel, and
- Clinical Laboratory Scientist - Specialists.

The education and examination requirements are outlined in the draft, with alternative approaches to licensure for each category;

Require all other individuals performing laboratory tests (known as "limited function lab testing") to be trained in the specific tests they will be performing, and certified by the trainer;

Establish a board to set policy, or an advisory committee to advise the Secretary in setting policy. The Department of Health would administer the program.

Exempt individuals licensed under other health professions from the licensing requirement, provided they only function within their own scope of practice. Exempt employees of the federal government, teachers, researchers, students, trainees, business managers, and personnel in waived medical test sites;

Place the licensees under the regulation of the Uniform Disciplinary Act;

Require the program to be self-supporting through fees.

SUMMARY OF EVIDENCE AND FINDINGS

The department's sunrise review committee considered information provided by proponents and opponents in light of the sunrise criteria. This section summarizes the information provided and the conclusions drawn. The information is provided in its entirety in a three volume appendices, a copy of which is provided to the legislature and the Office of Financial Management, and is available to the public at the cost of copying.

Potential harm to the public:

Information from Applicant Group

Documentation and studies were provided that show that laboratory tests play a key role in the diagnosis and treatment of illness and medical conditions. Information provided by the applicant group states there is harm to the public due to inadequate and unregulated laboratory testing ranging from wasted time and money to emotional turmoil, erroneous treatment and even death. The applicant maintains that inadequately trained, nonmedical personnel using lab equipment, working under

unsanitary conditions pose a real threat of transmitting infectious disease. Additionally, the group maintains that hardship and death have been caused by inaccurate and inadequate performance of laboratory tests. The applicant group states that unregulated practice can result in misdiagnosis of a patient's condition by untrained personnel leading to inappropriate treatments or medications. The general supervision of these laboratories by physicians is often ineffective because most physicians have had little training in laboratory analysis, and generally have a limited understanding of the complexities of testing and may not be able to detect unreliable results, which may lead to a misdiagnosis.

Committee Findings/Conclusions

The committee concluded that the applicant group demonstrated that the lack of regulation of laboratory testing increases the risk of poor quality outcomes in testing. However, the information provided did not conclusively show that the recently established regulatory programs, under the authority of (Washington State), Chapter 70.42 RCW, Medical Test Site Act and the Federal Clinical Laboratories Improvements Act, (CLIA '88) are not adequate to address the problems that were stated to be occurring.

Consumers Need and Benefit:

Information from Applicant Group

Information provided by the applicant group states that consumers have little knowledge or means of knowing where laboratory testing is being performed, if tests are performed correctly, or if tests are being performed by qualified personnel. The applicant group stated that minimum educational standards and performance levels are needed to protect the public from harm. Additionally, the applicant group states that strict personnel standards under CLIA '88 would severely impact the delivery of health care in our state. The applicant group also noted that CLIA '88 would grant a waiver to these personnel requirements if the state licenses these practitioners.

Committee Findings/Conclusions

Again, the committee found that the existing State Medical Test Site Act and Federal CLIA '88 regulations had not been given an opportunity to work. These laws require licensing of laboratory facilities, inspection and review of proficiency testing data. Inspections and review of the proficiency data only began in January 1991. There is concern that the real cost of establishing these personnel standards is unknown as definitive information regarding the number, types and current training of personnel was not available. Establishing personnel standards could require small clinics to hire several licensed people to do what one generalist presently does. Flexibility of

what procedures could be performed would be limited and costs could be increased. Personnel standards could cause salaries in this occupation to increase, increasing costs to clinics and eventually consumers. Additionally, a scarcity of qualified personnel could affect the rural areas, possibly forcing them to close. Although the applicant group contends that establishment of a licensure law would waive strict personnel requirements under CLIA '88, the department's interpretation is that the state will avoid federal regulation only if its own requirements are at least as strict as the federal requirements.

Efforts to Address the Problem:

Information from Applicant Group

Information provided by the applicant group states that the Washington State Society for Medical Technology (WSSMT) and the Washington State Society for American Medical Technologists (WSSAMT) have a mission to assure adequate standards of practice through research, consensus, education, publication and government activities. However, they note that there is inadequate compliance in laboratories which are not required to meet federal regulations on personnel. They maintain that until recent years the societies were effective in maintaining adequate competency of clinical laboratory science practitioners. However, the expansion of laboratory testing and availability of instrumentation and simplified methodologies have made it seem possible for testing to be performed by personnel who lack even

basic understanding of laboratory sciences. The simplicity of some modern instrumentation has deceived providers and the public into believing that reliable and accurate results are automatic. The applicant group states that present federal regulations do not completely address the problems of testing since they only set requirements for personnel in interstate laboratories and that the state's site licensure law does not impose any regulations on personnel. Consequently, regulation of laboratory testing is uneven and inadequate.

Committee Findings/Conclusions

Given the information provided, the sunrise review committee could not conclusively determine that the public could not be effectively protected by other means in a more cost-effective manner. The committee expressed concern that specific information was not available to determine the actual cost of regulating this profession. Opponents argued that the establishment of personnel standards by the state would be costly and unnecessary. Again it was noted that the State Medical Test Site Act and Federal CLIA '88 regulations had not had an opportunity to demonstrate their effectiveness.

Other Means of Regulation:

Information from Applicant Group

The applicant group noted that regulation of laboratory facilities, where it exists, has been effective in improving the quality of laboratory test results. However, a significant and increasing proportion of laboratory testing is being performed outside of the present regulated environment. Voluntary compliance with accepted training and education standards for laboratory practice at these sites has been ineffective and resulted in the passage of CLIA '88. The applicant group notes that the impact of CLIA '88 is not yet clear in the area of personnel standards and being a facility licensure law, it does not deal appropriately with personnel requirements. They note that personnel regulations proposed under CLIA '88 are viewed as being very restrictive, inflexible and burdensome, particularly in rural areas. The applicant group proposes that licensure or certification of personnel by the State of Washington would provide maximum flexibility with minimal cost burden. They also maintain that this proposal to license laboratory practitioners is the state's opportunity to set its own standards for laboratory personnel and to minimize the potentially disruptive impact of federal regulation.

Committee Findings/Conclusions

The committee found much disagreement among individuals who provided information on the final CLIA '88 wording regarding

personnel standards, relating to restrictiveness and inflexibility. Agreement could not even be reached as to when these rules would be adopted. The applicant group noted that licensure or certification would provide maximum flexibility with minimal cost burden. However, the information provided by the applicant group was insufficient to determine costs of regulation, cost of educating or training of individuals not meeting requirements for licensure, impact on educational programs, impact on access to care, or impact on the supply of personnel.

Public Benefits from Regulation:

Information from Applicant Group

The applicant group notes that reduction or elimination of unqualified practitioners will improve the accuracy and reliability of laboratory testing and result in improvements in the effectiveness of medical decisions based on such testing. The public would benefit from knowing the qualification of those persons performing their laboratory tests as licensure would mandate all personnel meet certain requirements. Training, experience, certification requirements and examinations would vary depending on the level of licensure or certification required. Requirements would range from high school graduates, with limited training and experience who could meet the requirements for certification as a laboratory assistant, to Ph.D. scientists, with years of education, training and

experience who would meet the requirements for licensure as clinical laboratory scientists or specialists. It is not expected that this legislation will cause any significant increase in training programs or the cost of training in the near future. Although, over the long term, licensure will increase enrollment in present programs which are now under-subscribed. In order to assure continued competency, a licensee would be required to submit proof of twenty hours of approved continuing education or proof of recertification by an approved agency.

Committee Findings/Conclusions

Information received from other sources propose that modern technology has produced laboratory equipment that is so sophisticated that great skill on the part of laboratory personnel is not required to run it. Increasing reliability of laboratory tests due to improvement in technology means that there is less need for the establishment of personnel standards in the field of medical technology. Additionally, this information proposes that doctors do not base a diagnosis solely on the basis of any laboratory test or series of laboratory tests. Laboratory tests are merely an adjunct to other diagnostic techniques and devices and the laboratory is confirmatory, not diagnostic. Although this may be true, the committee concluded that individuals performing laboratory tests do need to be adequately trained to perform laboratory testing. Simplified tests and improved instructions cannot completely substitute for personalized training. However, the applicant